REMARKS

Claims 3, 14-17, 19, 20, 23, 26, 27, 30, 39, 40, and 60-68 are currently pending. To expedite prosecution and to reduce the number of issues for appeal, claims 4, 17, 19, 23, 30, 39, 40, 60, and 63-68 have been canceled without prejudice. Therefore, claims 3, 14-16, 20, 26, 26, 27, 61, and 62 will be pending upon entry of this amendment.

Independent claims 3 and 20 have been amended to specify that:

(a) the composition includes a "pharmaceutically acceptable carrier"

(b) the first polypeptide is a "human" polypeptide and is "selected from the group consisting of CD79α, CD79β and CD20" and

(c) the second polypeptide is an "Fc fragment of a non-human immunoglobulin molecule."

Support for the amendments to claims 3 and 20 can be found throughout the specification as originally filed, for example, at page 40, lines 14-21, and original claims 4, 17, and 19.

Dependent claims 14, 61, 62, and 68 have been amended to provide proper antecedent basis.

The foregoing amendments should in no way be construed as an acquiescence to any of the Examiner's rejections, and have been made solely to expedite examination of the present application and to place the pending claims in better condition for appeal. No new issues have been raised and no additional search should be required. Accordingly, Applicants respectfully request that the foregoing claim amendments be entered. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s). No new matter has been added.

Rejection of Claims 3, 4,14-17,19, 20, 26, 27, 30, 39, 40, 60-62, 65, 67, and 68 Under 35 U.S.C. §112, First Paragraph

Claims 3, 4, 14-17, 19, 20 26, 27, 30, 39, 40, 60-62, 65, 67, and 68 are rejected under 35 U.S.C. §112, first paragraph, as not being enabled or as not meeting the written description requirement. Specifically, the Examiner states that the specification

> does not reasonably provide enablement [nor does it reasonably provide a written description] for *any* immunogenic composition comprising *any* "first polypeptide" which is autologous to any subject or which is immunologically cross-reactive with the autologous polypeptide coupled to *any* "second polypeptide," which is heterologous to the subject, wherein the first polypeptide comprises any immunogenic portion of any polypeptide specifically expressed on the surface of activated B cells and wherein the second polypeptide contains at least one T helper cell epitope, the composition being capable of eliciting any immune response against B cells in the subject. . . (emphasis in original)

However, the Examiner admits that the specification is enabling and does provide a written description for

> an immunogenic composition comprising a first polypeptide which is autologous to a subject, coupled to a second polypeptide, which is heterologous to the subject, wherein the first polypeptide is specifically expressed on the surface of activated B cells selected from the group consisting of CD79α, CD79β, and CD20, and wherein the second polypeptide is the Fc fragment of Ig heterologous to a subject and contains at least one T helper cell epitope, the composition being capable of eliciting an antibody immune response against B cells in the subject. ..

From this, the Examiner concludes that "making and using the claimed composition for treating any disease would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue." The Examiner also concludes that "Applicant was not in possession of the claimed genus."

Applicants respectfully traverse this rejection. However, to expedite prosecution and to reduce the number of issues for appeal, the claims have been amended to recite the subject matter which the Examiner deems enabled and supported by the specification, *i.e.*, the claims have been amended to specify that the first polypeptide is selected from the group consisting of CD79α, CD79β, and CD20, and wherein the second polypeptide is an Fc fragment of a non-human immunoglobulin molecule.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejections of the claims under 35 U.S.C. §112, first paragraph, as not being enabled and as not providing an adequate written description.

Rejection of Claims 3, 4,14-17,19, 20, 26, 27, 30, 39, 40, 60-62, 65, 67, and 68 Under 35 U.S.C. §112, Second Paragraph

Claims 3, 4, 14-17, 19, 20, 26, 27, 30, 39, 40, 60-62, 65, 67, and 68 are rejected under 35 U.S.C. §112, second paragraph, as being "indefinite in the recitation of 'composition'." The Examiner states that "[minimally, a carrier should be recited . . ."

The claims have been amended to specify that the compositions include a pharmaceutical acceptable carrier. Accordingly, this aspect of the rejection is now moot.

Claims 40, 61, and 62 are further rejected for lacking antecedent basis. Claim 40 has been canceled and claims 61 and 62 have been amended to depend from claim 20, as suggested by the Examiner. Accordingly, this aspect of the rejection is now moot.

Rejection of Claims 3, 4,16,17, 20, 39, 61, 62, 65, and 67 Under 35 U.S.C. §102(b)

Claims 3, 4, 16, 17, 20, 39, 61, 62, 65, and 67 are rejected under 35 U.S.C. §102(b) as being anticipated by Eberl *et al.* In particular, the Examiner states that

> Eberl *et al.* teach an immunogenic composition comprising a first polypeptide such as anti-CD 19 that is immunologically cross-reactive to autologous polypeptide CD 19 and CD20 that is expressed on the cell surface of B cells in a subject coupled or conjugated to a second polypeptide that is heterologous to the subject comprising a T helper epitope such as P2 derived from tetanus toxin peptide . . .

Applicants respectfully traverse this rejection. However, to expedite prosecution and to reduce the number of issues for appeal, independent claims 3 and 20 have been amended to incorporate the subject matter of claim 19, to which this rejection does not apply. Therefore, this rejection is now moot.

Rejection of Claims 3, 4,14,19, 20, 26, 27, 30, 39, and 60 Under 35 U.S.C. §102(b)

Claims 3, 4, 14, 19, 20, 26, 27, 30, 39, and 60 are rejected under 35 U.S.C. §102(b) as being anticipated by Lane *et al.* Specifically, the Examine states that

> Lane *et al.* teach an immunogenic composition comprising a first polypeptide such as the extracellular portion of the mouse CTLA-4 that is autologous to the subject fused to a second polypeptide that is heterologous to the subject such as the constant region of human IgGl (see abstract, in particular). The reference immunogenic composition is capable of eliciting an immune response such as inhibiting antigen presentation and induction of tolerance . . .

Applicants respectfully traverse this rejection. However, to expedite prosecution and to reduce the number of issues for appeal, independent claims 3 and 20 have been amended to incorporate the subject matter of claim 17, to which this rejection does not apply. Therefore, this rejection is now moot.

Rejection of Claims 17, 20, 65, and 67 Under 35 U.S.C. §103(a)

Claims 17, 20, 65, and 67 are rejected under 35 U.S.C. §103(a) as being unpatentable over Eberl *et al.* in view of Hashimoto *et al.* or Kooten *et al.* The Examiner refers to the teachings of Eberl *et al.* discussed above and admits that the invention recited in claims 17, 20, 65, and 67 "differs from the teachings of [Eberl *et al.]* only in that the first polypeptide comprises a portion of a molecule selected from the group consisting of CD79α, CD79β, and Ig." The Examiner further states that, based on the teachings of the secondary references,

> it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the anti-CD 19 or CD20 as taught by Eberl *et al.* for the CD79α (Ig-a-/mb-1) as taught by Hashimoto *et al.* or the Ig-β (B29 or CD79β) as taught by Kooten *et al.* for an immunogenic composition comprising a first polypeptide which is a mouse CD79α or CD79β coupled to a second heterologous polypeptide such as a T helper epitope derived from tetanus toxin for eliciting an immune response against B cells in the subject. . .

Applicants respectfully traverse this rejection. However, to expedite prosecution and to reduce the number of issues for appeal, claims 17, 65, and 67 have been canceled. Therefore, this rejection is now moot as it pertains to claims 17, 65, and 67. Further, claim 20 has been amended to incorporate the subject matter of claims 4 and 19, to which this rejection does not apply. Accordingly, this rejection is now moot.

Rejection of Claims 3, 14,15,17, 20, 30, 65, and 67 Under 35 U.S.C. §103(a)

Claims 3, 14, 15, 17, 20, 30, 65, and 67 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lane *et al.* in view of U.S. Patent No. 5,116,964 and Hashimoto *et al.* The Examiner refers to the teachings of Lane *et al.* and admits that the invention recited in claim 15 "differs from the teachings of [Lane *et al.]* only that the composition wherein the fusion protein is dimeric [sic]." The Examiner further admits that the invention recited in claims 17, 65, and 67 "differs from the teachings of [Lane *et al.}* only that the first polypeptide comprises at least a portion of a molecule selected from the group consisting of CD79α, CD79β and Ig." The Examiner still further admits that the invention recited in claim 30 "differs from the teachings of [Lane *et al.]* only that composition wherein the second polypeptide comprises at least a portion of an Fc region of an immunoglobulin [sic]."

> The Examiner contends that, based on the teachings of the secondary references,
>
> it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the mouse CTLA-4 as taught by Lane *et al.* for the mouse CD79oc (Ig-cc-/mb-l) as taught by Hashimoto *et al.* or the Ig-β (B29 or CD79β) as taught by Kooten *et al.* for an immunogenic composition comprising a first autologous polypeptide which is a mouse CD79α or CD79β coupled to a second heterologous polypeptide such as human Fc as taught by Lane *et al.* . ..

Applicants respectfully traverse this rejection. However, to expedite prosecution and to reduce the number of issues for appeal, independent claims 3 and 20 have been amended to include the subject matter of claim 4, to which this rejection does not apply. Accordingly, this rejection is now moot.

Rejection of Claim 40 Under 35 U.S.C. §103 (a)

Claim 40 is rejected as being unpatentable in view of Lane *et al.* in view of Hashimoto *et al.* or Kooten *et al.* and further in view of Isaacs *et al.* Applicants respectfully disagree. However, to expedite prosecution and to reduce the number of issues for appeal, claim 40 has been canceled. Therefore, this rejection is now moot.

Rejection of Claim 68 Under 35 U.S.C. §103(a)

Claim 68 is rejected as being unpatentable in view of Eberl *et al.* in view of Harlow *et al.* Applicants respectfully disagree. However, to expedite prosecution and to reduce the number of issues for appeal, claim 68 has been canceled. Therefore, this rejection is now moot.

Rejection of Claim 68 Under 3 5 U.S.C. §103 (a)

Claim 68 is rejected as being unpatentable in view of Lane *et al.* in view of Harlow *et al.* Applicants respectfully disagree. However, to expedite prosecution and to reduce the number of issues for appeal, claim 68 has been canceled. Therefore, this rejection is now moot.

C ONCLUSION

Based on the foregoing, the claims are in condition for allowance. If a telephone conversation with Applicant's attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicant's attorney at (617) 227-7400.

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Respectfully submitted,

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